

**REDACTED DOCUMENTS RELATING
TO DOCKET 5801**

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CONSULTING AGREEMENT

THIS AGREEMENT, dated the (4th) day of (February), 2005 (hereinafter "EFFECTIVE DATE"), between BARD PERIPHERAL VASCULAR, INC. an Arizona corporation having offices at 1625 West 3rd Street, Tempe, Arizona 85281 (hereinafter "BARD"), and (Thomas Kinney, MD) an individual, having a mailing address at (500 W. Harbor Drive #1308 San Diego CA 92107) (hereinafter "INDIVIDUAL")

WITNESSETH

WHEREAS, INDIVIDUAL has certain technical knowledge and experience with regard to the use of BARD PRODUCTS (hereinafter defined), and BARD wishes to utilize such technical knowledge and experience to provide training to other physicians in the field; and
 NOW, THEREFORE, in consideration of the terms and provisions set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is acknowledged by the execution and delivery hereof, BARD and INDIVIDUAL agree as follows:

1. Consulting Services.

(a) General. BARD hereby retains INDIVIDUAL to conduct on BARD's behalf, certain training courses respecting PRODUCTS (hereinafter "CONSULTING SERVICES") as BARD may reasonably request, and INDIVIDUAL hereby agrees to render CONSULTING SERVICES to BARD, all in accordance with and subject to the terms and provisions of this Agreement. "PRODUCTS" shall mean and include any of those current BARD products, including but not limited to (1) Recovery Filters and Recovery Cones.

(b) Time and Place. CONSULTING SERVICES shall be rendered by INDIVIDUAL as BARD may reasonably request and the parties hereby agree that the nature, extent, duration, time and place of such CONSULTING SERVICES shall be agreed by the parties in advance, taking into account INDIVIDUAL's other professional commitments. Notwithstanding the foregoing, INDIVIDUAL agrees to perform the following CONSULTING SERVICES: (i) conduct between (2) (1) (1) (1) (1) training courses regarding PRODUCTS during the TERM (hereinafter defined), each course to consist of (1) day at a location to be approved by BARD and shall include between (1) physician attendees ("TRAINING SESSION"). INDIVIDUAL agrees to implement those teaching materials and presentation materials as provided by BARD into the course. All sessions shall include a discussion of off-label use of a BARD product while rendering CONSULTING SERVICES on behalf of BARD.

(c) Consulting Fees. During the TERM hereof, BARD shall pay [REDACTED] in accordance with the terms of this Agreement but no more than an aggregate of (One) (1) TRAINING SESSIONS during the [REDACTED]

(d) Payment of Expenses. BARD shall promptly reimburse INDIVIDUAL for his/her reasonable out-of-pocket expenses approved in advance by BARD for housing, travel and meals (if any) and any other reasonable out-of-pocket expenses approved in advance by BARD incurred by INDIVIDUAL incident to his/her rendering of CONSULTING SERVICES hereunder, upon INDIVIDUAL's submission of appropriate written vouchers or receipts as are reasonably satisfactory to BARD.

(e) Independent Contractor. INDIVIDUAL shall be deemed to be, and function as, an independent contractor of BARD under this Agreement. INDIVIDUAL shall have no authority to act on BARD's behalf or to commit BARD to any course of conduct, and shall make no representation to the contrary to any person or entity not a party hereto.

(f) Representation and Warranty. INDIVIDUAL represents and warrants to BARD that he/she is not a party to any agreement or understanding effective on the EFFECTIVE DATE or applicable during the TERM of this Agreement, relating but not limited to, his/her current employment arrangement, restricting or limiting his/her ability to observe and perform the terms and provisions hereof on his/her part to be observed and performed.

2. Compliance with Laws.

(a) INDIVIDUAL shall conduct the CONSULTING SERVICES and maintain records and data in strict compliance with the TERM of this Agreement in accordance with all applicable laws and regulations, including without limitation the applicable requirements of the FDA.

(b) INDIVIDUAL will be responsible for obtaining all necessary approvals from those locations or facilities in which the CONSULTING SERVICES will be performed as well as appropriate patient informed consents and authorizations. INDIVIDUAL shall provide copies of all approvals, informed consents and/or authorizations to BARD prior to rendering the CONSULTING SERVICES. INDIVIDUAL agrees to comply with applicable U.S. state and federal laws and regulations relating to the security, protection and privacy of individually identifiable health care information, including without limitation the U.S. Federal Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder, as they may be amended from time to time.

3. Confidential Information. During the TERM of this Agreement and thereafter, INDIVIDUAL shall not use, disclose or disclose to any third party any trade secrets or confidential information received from BARD unless such information becomes generally known to the public through no fault of INDIVIDUAL.

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4. **Indemnification.** INDIVIDUAL shall indemnify and hold BARD harmless from and against any damage, liability, claim or suit (including reasonable attorneys' fees and court costs) arising from or incident to his/her misrepresentation of any representation or breach of any warranty made in this Agreement or his/her failure to observe and perform any term or provision of this Agreement on his/her part to be observed and performed. With respect to any such claim or suit, BARD shall promptly notify INDIVIDUAL thereof, and, if so requested, INDIVIDUAL shall also defend same, using counsel of his/her own selection but approved by BARD, and keep BARD reasonably informed as to the status of such defense.

5. **Term.** This Agreement will commence on the EFFECTIVE DATE and terminate one (1) year thereafter (the "TERM"), unless sooner terminated as provided in Section 6. This Agreement may thereafter be renewed between the parties upon an agreement in writing.

6. **Termination.**

(a) **Automatic Termination.** This Agreement shall automatically terminate:

- (1) At BARD's written election given to INDIVIDUAL, in BARD's sole judgment, upon his/her misrepresentation of any representation or breach of any warranty made herein; or
- (2) Upon INDIVIDUAL's death or, in BARD's sole judgment, INDIVIDUAL's physical or mental inability to observe and perform the terms and provisions of this Agreement on his/her part to be so observed and performed for a consecutive thirty (30) day period.

(b) **Termination for Cause.** Upon BARD's or INDIVIDUAL's failure to observe and perform any term or provision hereof on their respective part to be observed and performed, the non-defaulting party shall have the right to give that party notice thereof, and that party shall then have thirty (30) days to cure same. If such default is so cured, this Agreement shall remain in force and effect; if same is not cured within such period, then at the written election of the party giving such notice, this Agreement shall terminate.

7. **No Referrals.** BARD hereby agrees that, during the TERM of this Agreement, BARD shall not knowingly or willfully engage in any activity or request or suggest to INDIVIDUAL that he engage in any activity which would violate any provision of 42 U.S.C. §1320c-7b(b), as interpreted by 42 C.F.R. Pt. 1000, et seq., as amended (hereinafter collectively referred to as the "Statute"). INDIVIDUAL hereby agrees that, during the TERM of this Agreement, INDIVIDUAL shall not knowingly or willfully engage in any activity or request or suggest to BARD that BARD engage in any activity which would violate the Statute.

8. **Use of Other Products.** BARD hereby expressly acknowledges and agrees that nothing contained herein is intended to prohibit or restrict, nor shall any provision hereof be construed in a manner as prohibiting or restricting INDIVIDUAL's right to utilize, in his/her sole discretion, any product manufactured or service provided by any third party.

9. **Miscellaneous.** This Agreement constitutes the entire agreement between BARD and INDIVIDUAL respecting the subject matter hereof, and same may not be changed or modified except upon an instrument in writing between them which states that it is an amendment hereto. All of INDIVIDUAL's representations and warranties made in this Agreement, and all terms and provisions hereof intended to be observed and performed by BARD or INDIVIDUAL after the date of termination hereof, shall survive such expiration or termination and continue, thereafter, in full force and effect. BARD's right of indemnification and BARD and INDIVIDUAL's respective right of termination provided in this Agreement shall not be the exclusive remedies of such parties in the event of any misrepresentation, breach or default hereunder, and shall be in addition to any other remedies accorded either of them at law or in equity. This Agreement may not be assigned by INDIVIDUAL without the prior written consent of BARD. This Agreement shall be construed and enforced under and governed by the public laws of the State of Arizona without regard to its rules on conflicts of law.

IN WITNESS WHEREOF, BARD has caused this Agreement to be executed by its duly authorized officer and INDIVIDUAL has set his/her hand both on the date and year first above written.

BARD PERIPHERAL VASCULAR, INC. INDIVIDUAL:

By: _____

John D. McDermott
Title: President

(Thomas Kinney, M.D.)

EXHIBIT 5



**Bard Peripheral Vascular Division
Remedial Action Plan
Recovery Filter: Detached Limbs
SPA-04-04-01
July 12, 2004**

I. Product Description and Intended Use

- a. The Recovery Filter consists of twelve shape memory nitinol wires emanating from the central nitinol sleeve. These twelve wires form two levels of filtration. The legs provide a lower level of filtration and fixation to the caval wall. The arms provide the upper level of filtration and help center the filter in the vessel. The Recovery Filter is intended to be used in vena cava circular diameters up to 28 mm.

The Recovery Filter Delivery System consists of a 7 French I.D. introducer sheath and dilator, the Recovery Filter, a storage tube with saline infusion port, and a pusher system. The Recovery Filter is packaged pre-loaded within the delivery storage tube.

- b. The Recovery Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent filter or be implanted temporarily to treat the temporary risk of pulmonary embolism. The Recovery Filter has the following indications for placement:

1. Pulmonary thromboembolism when anticoagulants are contraindicated.
2. Failure of anticoagulant therapy in thromboembolic disease.
3. Emergency treatment following massive pulmonary embolism where the anticipated benefits of conventional therapy are reduced.
4. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

II. Manufacturer / Distributor

- a. The product is manufactured by the Bard Glens Falls Operation, Queensbury, NY and distributed by the Bard Peripheral Vascular, Inc. through the Bard Distribution Center, Covington, GA.

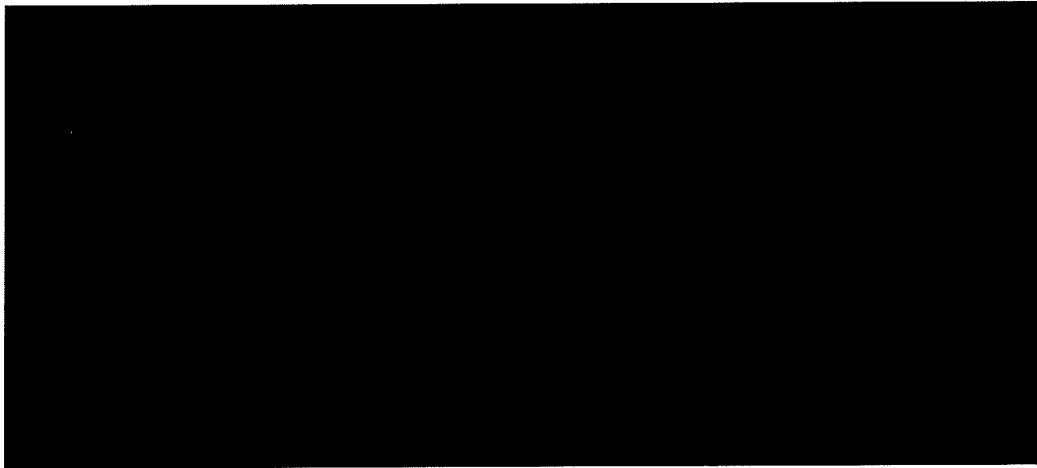
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III. Identification of the Problem:

- a. The first broken arm and hook was reported as an incidental finding during a routine filter removal in April, 2002. This was a patient in the Special Access program in Canada. This filter was placed in a pregnant patient and removed after the delivery of the baby. The filter and the arm were removed successfully. The hook was missing and not seen on X-Ray. The filter was manufactured by Nitinol Medical Technologies (NMT). The filter was placed below the renal veins. The IFU includes a precaution: "The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age".



IV. Medical Evaluation:

- a. See Health Hazard Evaluation report attached.

V. Number of units and lots involved:



VI. Distribution of Units

- a. Recovery Filters are being distributed in the United States, United Kingdom, Canada and Australia.

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